

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Harbige et al.	)	Group Art Unit: Not yet assigned
	)	
Application No.: 10/555,757	)	Examiner: Not yet assigned
	)	
Filed: November 7, 2006	)	
	)	
For: USE OF TRIGLYCERIDE OILS	)	Confirmation No.: 2532
CONTAINING GAMMA-	)	
LINOLENIC ACID RESIDUES AND	)	
LINOLEIC ACID RESIDUES FOR	)	
THE TREATMENT OF	)	
NEURODEGENERATIVE	)	
DISEASE	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.47 OF MR. TARIQ OSMAN**

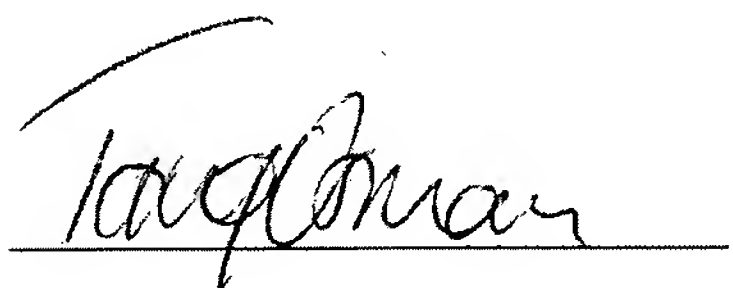
I, TARIQ OSMAN, do hereby declare and state as follows:

1. I am vice president at BTG International, Ltd. ("BTG"). I have been employed at BTG for 13 years.
2. U.S. Application No. 10/555,757 ("the '757 application") lists Laurence S. Harbige, Michael J. Leach, Mohammed Sharief, and Paul Barraclough as inventors.

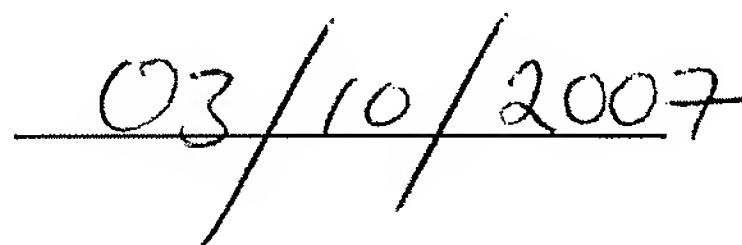
3. To the best of my knowledge, Sharief's last known work address is:  
  
Department of Neurology  
Colchester General Hospital  
Gainsborough Wing  
Colchester  
CO4 5JL England
4. In an email dated September 28, 2007, to Tony Dolan of BTG (Exhibit A), I described several attempts to contact Sharief by myself, and others, to have Sharief execute a declaration for the '757 application. My three attempts are described in points 5 and 6 below.
5. On November 29, 2006, I called Sharief on his mobile phone and left a voicemail. I indicated that BTG would like to update him on their work regarding clinical trials and would welcome the chance to speak with him. I did not mention anything about executing the declaration for the '757 application, which I intended to bring up in our conversation if he called me back. I did not receive a response to my message.
6. On June 13, 2007, I called Sharief's office, but was directed to his secretary's voicemail. I left a message and continued to try to reach him over the course of the week. On June 27, 2007, I spoke with Sharief's secretary, who indicated that she would pass my contact information on to him. I did not receive a response to my messages.
7. On July 25, 2007, I mailed a copy of the '757 declaration and the '757 application to Sharief at his work address and asked him to execute the declaration (Exhibit B). Exhibit C is a copy of my cover letter forwarding the

application and declaration for the '757 application for his execution. The documents were sent by United Postal Service ("UPS"). While UPS confirmed receipt by Colchester Hospital (Exhibit D), Sharief has not responded to this request for his execution of the documents.

I further declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true, and understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and may jeopardize the enforceability of any patent issuing from the '757 application.

A handwritten signature in black ink, appearing to read "Tariq Osman", written over a horizontal line.

Tariq Osman

A handwritten date "03/10/2007" written in black ink over a horizontal line.

Date

# EXHIBIT A

EXHIBIT A

**Tariq Osman**

---

**From:** Tariq Osman  
**Sent:** 28 September 2007 19:03  
**To:** Tony Dolan  
**Subject:** Mo Sharief

**1) Tariq Osman**

**Attempt 1**

Called at roughly 19:24, on 29 Nov 06.

I called the mobile Dr. Sharief gave me when we met last (07974109063).

Although not verbatim – I said BTG would like to move on with 0134 and take it in to clinical trials. We would like to give him an update to our work and that we would like to seek his advice on some aspects (CTA). I would welcome to hear back from him via my mobile or office phone or email and would welcome the chance to meet to discuss developments

**Attempt 2 – see email below**

**Sent:** 13 June 2007 12:20  
**To:** Tony Dolan; Paul Mussenden; Malcolm Carter  
**Cc:** Carol Routledge; Russell Hagan  
**Subject:** Dr. Sharief update

Dear all,

I've now rang Mohammad Shareif's office a number of times.

The main switch board directs calls to Mo to his secretary Jenny. (She works from 8am to 2:30pm Monday to Friday.)

This line is constantly on voicemail – the message saying "this is Jenny – Mohammad's secretary, I'm either on the line or away from my desk and hence pls leave a recorded message and I'll get back to you."

So I've now left a message and my number asking for Mo to contact me so we can give him a project update.

I'll keep on trying the number for the rest of the week and I'll let you know if I actually get to speak to him.

**Attempt 3 – email sent Wed 27/06/2007 10:09 saying**

"Just spoke to Mo's Pa – Jenny at Colchester General Hospital - Department of Neurology.

He's doing his rounds today (nearly finished his first morning round) so she will pass my contacts details and email over to Mo when he gets back into the office so he can return my call !!.

So let's wait and see if he does.

Cheers –T–"

**2) Emma Spencer**

**Attempt 1**

**From:** Emma Spencer  
**Sent:** 27 June 2007 10:11  
**To:** Tariq Osman; Russell Hagan; Tony Dolan; Carol Routledge; Paul Mussenden  
**Subject:** RE: Well - success for sorts - Mo Sharief

03/10/2007

I just called his mobile, which was off, but I left a message – fingers crossed!

**3) Paul Mussenden**

**Attempt 1**

Jane Ensor from Howrey (lawyer representing Dr. Sharief). Jane emailed Paul (12 March 2007 18:43) saying she had emailed Dr Sharief on Saturday having picking up Pauls' email message on Friday evening. Jane email said Dr Sharief had stated that he would contact you 9Paul), but I will also forward to him your email below.

"You will appreciate that I can do nothing more than forward your message to him and it will then be his decision as to when and if he contacts you."

# EXHIBIT B

## EXHIBIT B

604-756  
143884US02Nixon & Vanderhys P.C. (10/99)  
(Domestic Non-Assigned/Foreign) Page 1

**RULE 63 (37 C.F.R. 1.63)**  
**INVENTORS DECLARATION FOR PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

As a below named inventor, I hereby declare that my residence, mailing address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**USE OF TRIGLYCERIDE OILS CONTAINING GAMMA-LINOLENIC ACID RESIDUES AND LINOLEIC ACID RESIDUES FOR THE TREATMENT OF NEURODEGENERATIVE DISEASE**

the specification of which (check applicable box(es)):

☐ is attached hereto  
☒ was filed on November 7, 2005 as U.S. Application Serial No. Unassigned (Atty. Dkt. No. 604-756)  
☒ was filed as PCT International application No. PCT/GB2004/002089 on 14 May 2004  
 and (if applicable to U.S. or PCT application) was amended on

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose to the Patent Office all information known to me to be material to patentability as defined in 37 C.F.R. 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed or, if no priority is claimed, before the filing date of this application:

Priority Foreign Application(s): Application Number	Country	Day/Month/Year Filed
0311081.4	United Kingdom	14 May 2003
60/497,332	United States	25 August 2003

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

Application Number	Day/Month/Year Filed

I hereby claim the benefit under 35 U.S.C. 120/365 of all prior United States and PCT International applications listed above or below:

Prior U.S./PCT Application(s): Application Serial No.	Day/Month/Year Filed	Status: patented pending, abandoned
PCT/GB2004/002089	14 May 2004	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. And on behalf of the owner(s) hereof, I hereby appoint Nixon & Vanderhys P.C., telephone number 703-816-

4000 (to whom all communications are to be directed) and the attorneys of: **Customer Number 23117**, individually and collectively owner's/owners' attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent. I also authorize Nixon & Vanderhys to add or delete attorneys from that Customer Number, and to act and rely solely on instructions directly communicated from the person, assignee, attorney, firm, or other organization sending instructions to Nixon & Vanderhys on behalf of the owner(s).

1. Inventor's Signature: Inventor:	Laurence (first)	S. M	Harblge (last)	British (citizenship)	Date:
Residence: (city)	London				
Mailing Address:	40 Middleton Close, London, United Kingdom				
(Zip Code)	E4 8EA				
2. Inventor's Signature: Inventor:	Michael (first)	J. M	Leach (last)	British (citizenship)	Date:
Residence: (city)	Kent				
Mailing Address:	48 Cherry Tree Walk, West Wickham, Kent, United Kingdom				
(Zip Code)	BR4 9EF				

**[X] See attached sheet(s) for additional inventor(s) information!!**



604-756..  
Serial No. Unassigned  
Page 2

Nixon & Vanderhye P.C. (10/99)  
(Domestic Non-Assigned/Foreign)

3.	Inventor's Signature: _____ Inventor: _____ Residence: (city) _____ Mailing Address: _____ (Zip Code) _____	Mohammad (first)	MI	Sharief (last)	United Kingdom (state/country)	British (citizenship)	Date: _____
4.	Inventor's Signature: _____ Inventor: _____ Residence: (city) _____ Mailing Address: _____ (Zip Code) _____	_____	_____	_____	_____	_____	Date: _____
5.	Inventor's Signature: _____ Inventor: _____ Residence: (city) _____ Mailing Address: _____ (Zip Code) _____	_____	_____	_____	_____	_____	Date: _____
6.	Inventor's Signature: _____ Inventor: _____ Residence: (city) _____ Mailing Address: _____ (Zip Code) _____	_____	_____	_____	_____	_____	Date: _____

FOR ADDITIONAL INVENTORS, check box. [ ] and attach sheet with same information and signature and date for each.

# EXHIBIT C



DC: 500134

Confidential

Dr. Mohammad K. Sharief  
Department for Neurology  
Colchester General Hospital  
Gainsborough Wing  
Colchester  
CO4 5JL

Tariq Osman  
BTG International Ltd  
10 Fleet Place  
Limeburner Lane  
London  
EC4M 7SB

25 July 2007

Dear Mohammad,

I am sure you are as busy as ever but I hope that this letter finds you well and enjoying the work at Colchester General Hospital?

I have been trying to contact you for some time as I would like to discuss two matters with you.

The first matter relates to the developments at BTG surrounding one of your technologies. We are very happy to inform you that the BTG board agreed to fund the development of BGC20-0134 (the follow-on compound from BGC20-0884) and hence we are now quickly moving forward with the necessary preparations for a clinical trial. Currently we are finalising the IB and IMPD so that we can commence a Phase I study this coming October. Once completed and assuming the necessary end points are met, the BTG board has approved in principle further funding to take the compound into a Phase IIa study as quickly as possible.

Consequently, we would welcome the chance to appraise you face to face on this work, so we can have the opportunity to discuss with you various clinical matters surrounding the project to optimise its development as best we can. We have always appreciated the assistance and time you gave us when working on BGC20-0884, and hence we would again like to re-establish that dialogue with you to move BGC20-0134 forward.

The second matter I'd like to discuss with you is the patent assignments for the technology. To make sure we secure the best IP position for your technology we need to have these documents countersigned by you ASAP, so we can have them filed with the appropriate patent authorities. This is becoming critical as we need to make sure the patent situation is as robust as possible, so that we can continue to secure the necessary funding for this project to take it forward. The above commitment from BTG is conditional on resolving this patent administration issue. If we don't get these documents processed it will greatly reduce the chances of BTG (or anyone else) providing the financial support necessary to continue the development of this truly disease modifying technology, and to get it to the patients that need it.

BTG International Ltd

10 Fleet Place Limeburner Lane London EC4M 7SB T: +44 (0)20 7575 0000 F: +44 (0)20 7575 0010  
info@btgplc.com www.btgplc.com

Registered in England: No. 2664412 VAT No. GB 607 8167 28  
Registered Office: 10 Fleet Place Limeburner Lane London EC4M 7SB



To expedite matters, I've included the necessary documents that require your signature. To ease administration for you, I have included a BTG addressed envelope so you can quickly and simply return all the documents to BTG. I'd be very grateful if you could return these to me as soon as possible.

As I say we would greatly welcome the chance to meet you, to expand on the great strides BTG has made with your technology. BGC20-0134 has now become an important clinical project within BTG. We realise this would be an ideal time to reconnect with you so that we can discuss and optimise its continued development, to enable it to reach the patients you intended it for.

My contact details are below. We'd be very happy to host you at BTG, but we'd be happy to come to Colchester and discuss the work we have done to date if this would be more convenient

Very best wishes Mohammad

A handwritten signature in dark ink, appearing to read "Tariq", with a long horizontal stroke extending to the left.

-Tariq-  
BTG International Ltd

Mobile: 077 99 50 777 2

Email: [tariq.osman@btgplc.com](mailto:tariq.osman@btgplc.com)

**Enc:**

Our ref: 143884: Copy of International Application No. PCT/GB04/002089, as published  
Preliminary amendment as filed at the United States Patent & Trademark Office  
US Assignment document and Inventors Declaration document  
Canadian Assignment document – NB this document requires witnessing  
Spanish Assignment document  
Finnish Assignment document  
Swedish Assignment document

Our ref: 500134: Copy of International Application No. PCT/GB04/003524, as published  
Preliminary amendment as filed at the United States Patent & Trademark Office  
US Assignment document and Inventors Declaration document  
Canadian Assignment document – NB this document requires witnessing  
Chinese Assignment document  
Finnish Assignment document

Our ref: 500850: Copy of International Application No. PCT/GB05/004516, as published  
Appointment of agent document  
Preliminary amendment as filed at the United States Patent & Trademark Office  
US Assignment document and Inventors Declaration document



# EXHIBIT D

**Karen Murphy**

---

**From:** QuantumView [QuantumViewNotify@ups.com]  
**Sent:** 26 July 2007 10:44  
**To:** Karen Murphy  
**Subject:** UPS Delivery Notification, Tracking Number 1Z57A0496697487670

\*\*\*Do not reply to this e-mail. UPS and BTG International Limited will not receive your reply.

**At the request of BTG International Limited, this notice is to confirm that the following shipment has been delivered.**

**Important Delivery Information**

---

**Delivery Date / Time:** 26-July-2007 / 10:12 AM  
**Delivery Location:** Goods In  
**Signature Obtained**

**Shipment Detail**

---

**Ship To:**  
Colchester General Hospital  
Department of Neurology  
Gainsborough Wing  
Colchester  
Essex  
CO45JL  
GB

**UPS Service:** EXPRESS  
**Shipment Type:** Letter

**Tracking Number:** 1Z57A0496697487670  
**Reference Number 1:** 500134/500850/143884

---

This e-mail contains proprietary information and may be confidential. If you are not the intended recipient of this e-mail, you are hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If you received this message in error, please delete it immediately.

This e-mail was automatically generated by UPS e-mail services at the shipper's request. Any reply to this e-mail will not be received by UPS or the shipper. Please contact the shipper directly if you have questions regarding the referenced shipment or you wish to discontinue this notification service.

\_\_\_\_2IJKIIX8AvJRO\_\_\_\_